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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,185	06/24/2005	John Royle	0148/386US	8580
23638 7590 06/23/2009 ADAMS INTELLECTUAL PROPERTY LAW, P.A. Suite 2350 Charlotte Plaza 201 South College Street CHARLOTTE, NC 28244			EXAMINER PATEL, PRITESH ASHOK	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 06/23/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,185

Applicant(s)

ROYLE, JOHN

Examiner

PRITESH PATEL

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 46-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 46-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date _____
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 2, and 46-66 are rejected under 35 U.S.C. 103 (a) as being unpatentable over MacDonald et al. (US Patent 5776170).

Concerning Claims 1 and 2, MacDonald et al. discloses a pulse generating unit connectable to two electrodes able to provide a series of electrical pulses to a patient's body (Abstract). The pulse generating unit outputs positive and negative polarity pulses in series, each pulse width being around 10 microseconds and having a temporal spacing in between pulses (Column 3, Lines 60-67). MacDonald et al. discloses an impulse width of 10 microseconds (column 3 line 60). It would have been obvious to one of ordinary skill in the art at the time of the invention to pick a value of impulse width around the value of 10 microseconds and get the same therapeutic quality based upon MPEP 2131.03 : "[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims to titanium (Ti) alloy with 0.8% nickel (Ni) and 0.3% molybdenum (Mo) were not anticipated by, although they were held obvious over, a graph in a Russian article on Ti-Mo-Ni alloys in which the graph contained an actual data point corresponding to a Ti alloy containing 0.25% Mo

and 0.75% Ni.).

Concerning claims 64-66, MacDonald et al. discloses two electrodes connectable to a pulse generating unit that produces an analgesic effect by reducing pain via the central nervous system leaving the peripheral nervous system mildly affected or not at all (Abstract).

Concerning claims 46-51, MacDonald et al. discloses a spacing of 4 microseconds or more between impulses (column 3, line 61). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify MacDonald to use 4 or 6 or 10 or 20 microseconds of spacing between impulses. It would have further been obvious to one of ordinary skill in the art at the time of invention that a temporal space is inherent between a plurality of contiguous impulses, a majority of impulses, and all impulses.

Concerning claims 52-54, MacDonald discloses a square wave in a circuit whose pulse width is set by a variable resistor (Column 4, lines 39-42). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the circuit of MacDonald et al. to produce an impulse with an asymmetric shape or a peak magnitude of 30% or 5% or 1% of the pulse width depending on desired exposure of voltage of an impulse to a patient. It would have further been obvious to have a peak magnitude that is 70% of the pulse width to increase desired exposure of voltage to patient. The manipulation of a circuit is obvious to one of ordinary skill in the art at the time of the invention.

Concerning claims 55-57, MacDonald et al. discloses an amplitude of 180V or

more and an amplitude of 450V to 1kV (Claims 2 and 3 in MacDonald et. al.). It would have been obvious to one of ordinary skill at the time of the inventions to use voltage range from 150V to 250V or 50V to 450V for amplitude values for an electrode apparatus. It would further have been obvious to one of ordinary skill in the art at the time of the inventions to use equal voltage values for the negative and positive amplitudes to reduce strain on the apparatus.

Concerning claim 58, MacDonald discloses the use of temporal spacing in between impulses and series of pulses as seen in column 3, line 61. It would have been obvious to one of ordinary skill in the art at the time of the invention that during the spacing between impulses the output of the pulse generating unit remains at a level substantially equal to 0V.

Concerning claims 59, MacDonald discloses the use of frequency greater than 100 Hz and that typically the frequency of 150kHz is also usable (Claim 5 of MacDonald et al. and column 4, line 19; respectively). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a range of 100 Hz to 250 kHz or 1 kHz to 250 kHz or 1 to 5 kHz or 2 kHz to 3 kHz as applied to the use of the apparatus disclosed.

Concerning claims 60-63, MacDonald et al. discloses a series of pulses consisting of impulses with a temporal spacing as discussed before (column 3, line 61). It would have been obvious to one of ordinary skill in the art at the time of the invention to understand that a series of pulses can have third impulse spaced from the second impulse by a temporal spacing, and that a series of impulses are a series of intermittent

pulses. It would further have been obvious to one of ordinary skill in the art at the time of the invention to use a ratio of time period of no impulse to time period of impulse in the range of 1:3 to 1:20 to determine the length of time electrical impulses are delivered to the body and the time period of no pulse occurs at least once in a second as lasts for at least 0.5 millisecond. The obviousness of using the parameters discussed lies the inherency of use of a series of pulses and an electrode apparatus.

3. Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacDonald et al. in view of Effenhauser (US Patent 6032073).

Concerning Claims 67 and 68, MacDonald et al. discloses a method of using two electrodes connected to a pulse generating unit that provide a series of positive and negative impulses and a maximum voltage of 450V (abstract and column 3, lines 59). MacDonald et al. does not disclose the use of iontophoresis electrodes with a medication for delivery to the body. Effenhauser discloses the use of iontophoresis electrodes to deliver medication to the body for a therapeutic effect (Column 1, Lines 56-64).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify MacDonald et al. with iontophoresis electrodes as taught by Effenhauser. The power and variability in the pulse generating unit of MacDonald et al. could have enhanced the therapeutic effects of the device by providing simultaneous medication delivery. It would further have been obvious to utilize a 50 V amplitude during iontophoresis to reduce overdosing a patient.

Response to Arguments

4. Applicant's arguments filed 03/02/2009 have been fully considered but they are not persuasive. The declaration sent in by applicant was improper. Though the applicant's credentials are commendable, the mere utterance of a result without proof does not hold weight. To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960). The rejection stands as is and the actions is made final.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRITESH PATEL whose telephone number is (571)270-

7025. The examiner can normally be reached on Monday-Friday 7:30Am-5:00PM, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. P./
Examiner, Art Unit 3763
06/19/2009

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763